

**REMARKS**

Claims 1, 3, 8-22, 26, 27, 29, 30, 34-38, 40, 44-51 and 54-65 are pending.

Applicant has cancelled, without prejudice, Claims 11-13, 44-46 and 48-51.

Applicant has amended independent Claims 1, 17, 26 and 34 without prejudice with respect to any material no longer encompassed by the newly amended claims. These claim amendments further clarify the claimed invention by specifying that the claimed formulation is free of additional active components. Support for this amendment is found throughout the specification, particularly in paragraphs 50 and 55 of the published specification, where it is disclosed that "formulations of PACAP 66 may be used alone". No new matter has been added as a result of the amendments.

Applicant has further amended Claims 1 and 34, to specify that the zinc salt is  $\text{ZnCl}_2$ . Applicant has amended Claims 15 and 16, which previously depended from claim 11, to depend from Claim 1. Support for this amendment is found at least in the claims as originally filed.

Applicant submits that no new search is required as a result of these claim amendments.

***35 U.S.C. § 102(e) - Edmondson***

Claims 1, 3, 34-35, and 40 stand rejected under 35 U.S.C. 102(e) as being anticipated by Edmondson et al. (US Patent 7,125,873).

"Anticipation requires that the purported prior art reference disclose each and every limitation of the claim". *Atlas Powder Company et al. v. IRECO, Incorporated et al.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999).

Applicant respectfully traverses the rejection of the instant claims on the grounds that Edmondson et al. does not teach each and every limitation of the instant claims as newly amended.

Claim 1 and dependent claim 3, as newly amended, are drawn to a stabilized peptide formulation consisting essentially of the peptide PAP 66 or a salt thereof, a zinc salt, and a pharmaceutically acceptable organic solvent, where the zinc salt is  $\text{ZnCl}_2$  and where the

formulation is free of additional active components. Claim 34 and dependent claims 35 and 40, are drawn to a stabilized dried mixture consisting essentially of a zinc salt and the peptide PAP 66 or a salt thereof, where the zinc salt is  $\text{ZnCl}_2$  and where the formulation is free of additional active components.

Solely for the purposes of expediting prosecution, Applicant has reduced the scope of the claims by newly adding the limitation that the recited formulation is free of additional active components. Thus, a formulation comprising Compound I as taught by Edmonson et al. does not fall under the scope of the instant claims. Specifically, Edmonson et al. teaches a pharmaceutical composition that comprises two actives, a compound of Formula I and at least one of PACAP, PACAP mimetics, and PACAP receptor 3 agonists, as illustrated below:

“Accordingly, the pharmaceutical compositions of the present invention include those that contain one or more other active ingredients, in addition to a compound of Formula I. Examples of other active ingredients that may be administered in combination with a compound of Formula I, and either administered separately or in the same pharmaceutical composition, include, but are not limited to:

.....(i) PACAP, PACAP mimetics, and PACAP receptor 3 agonists such as those disclosed in WO 01/23420”, column 12, line 40 to column 13, line 4 of US 7,125,873.

In contrast to the instant claims which require the formulation be free of additional active components, the formulation taught by Edmonson et al. comprises the additional active component, Compound I. Further, in contrast to the instant claims which require the presence of a zinc salt in addition to PACAP, Edmonson et al. teaches a salt only with respect to Compound I. That is to say, Edmonson et al. does not teach a separate salt in addition to the salt of the Compound I. In contrast, the instant claims recite a separate zinc salt, in addition to the option of having a zinc salt of PACAP.

By teaching a formula that includes Compound I, the formulation of Edmonson et al. exceeds the scope of the claims as newly amended. Accordingly, Applicant submits that the Edmonson et al. reference does not qualify as an anticipatory reference.

In light of the above remarks and claim amendments, Applicant respectfully requests reconsideration of the rejection of the instant claims.

***35 U.S.C. § 103(a) - Claim 11***

Claim 11 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Edmondson et al. (US Patent 7,125,873).

Applicant respectfully traverses. To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

As discussed above, Claim 11 has been cancelled by Applicant without prejudice, solely for the purpose of advancing prosecution, rendering the rejection of claim 11 moot.

Applicant will address the rejection as it would apply to Claim 1, which as newly amended, is drawn to a stabilized peptide formulation, either in a solution or in a suspension, consisting essentially of: (a) PACAP 66 and/or salts thereof; (b)  $\text{ZnCl}_2$ ; and (c) a pharmaceutically acceptable organic solvent. Solely for the purposes of expediting prosecution, Applicant has reduced the scope of the claims by newly adding the limitation that the recited formulation is free of additional active components.

Edmonson et al. teaches a pharmaceutical composition that comprises a formulation of Compound I and at least one of PACAP, PACAP mimetics, and PACAP receptor 3 agonists. Thus, a formulation comprising Compound I as taught by Edmondson et al. does not fall under the scope of the instant claims as newly amended. Further, in contrast to the instant claims which require the presence of  $\text{ZnCl}_2$ ; in addition to PACAP, Edmonson et al. teaches a salt only with respect to Compound I. That is to say, Edmonson et al. does not teach a separate salt in addition to the salt of the Compound I. In contrast, the instant claims recite a separate zinc salt ( $\text{ZnCl}_2$ ), in addition to the option of having a zinc salt of PACAP.

Because the cited reference, Edmondson et al., exceeds the scope of the instant claims, and does not teach all the limitations of the claims as newly amended, a prima facie obviousness has not been established as required by *In re Royka*.

In light of the above remarks and claim amendments, Applicant respectfully submits that claim 1 is not obvious over Edmondson et al. (US Patent 7,125,873).

***35 U.S.C. § 103(a)- Claims 44-46 and 48-53***

Claims 44-46 and 48-53 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Oshaki et al. (US 5,428,129) in view of Thakur (US/2003 129133A1) and Edmondson et al. (US Patent 7,125,873).

In the interest of advancing prosecution, Applicant has canceled Claims 44-46 and 48-53, without prejudice, rendering their rejection moot.

***35 U.S.C. § 103(a)- Claims 1, 3, 8, 10-13, 15-20, 22, 26, 29-30, 34-37 and 40***

Claims 1, 3, 8, 10-13, 15-20, 22, 26, 29-30, 34-37 and 40 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Edmondson et al. (US 7,125,873) in view of Pallenberg et al. (US Patent No. 5,538,945) and Maccicchini (U.S. Patent 5,830,998) and Bolin (US 5,234,907) and Igari et al. (US 2002/0058622A1).

Applicant respectively traverses. As discussed above, Claims 11-13 have been cancelled by Applicant without prejudice. Also solely for the purposes of expediting prosecution, Applicant has reduced the scope of the claims by newly adding the limitation that the recited formulation is free of additional active components.

Claim 1 and dependent claim 3, 8, 10, 15 and 16, as newly amended, are drawn to a stabilized peptide formulation consisting essentially of the peptide PAP 66 or a salt thereof, a zinc salt, and a pharmaceutically acceptable organic solvent, where the zinc salt is  $ZnCl_2$ , and where the formulation is free of additional active components.

Claim 17 and dependent claims 18, 19 and 20, are drawn to a stabilized peptide formulation, consisting essentially of a dried mixture of an acid, the peptide PACAP 66 or a salt thereof, and a zinc salt, wherein said formulation is free of additional active components.

Claim 26 and dependent claims 29 and 30, are drawn to a stabilized peptide formulation, consisting essentially of a dried mixture of an inorganic acid, PACAP 66 (SEQ ID NO: 1) and/or a salt thereof, and a zinc salt, wherein said formulation is free of additional active components.

Claim 34 and dependent claims 35-37 and 40, are drawn to a stabilized dried mixture consisting essentially of  $\text{ZnCl}_2$  and the peptide PACAP 66 or a salt thereof, and where the formulation is free of additional active components.

Edmonson et al. teaches a pharmaceutical composition that comprises a formulation of Compound I and at least one of PACAP, PACAP mimetics, and PACAP receptor 3 agonists. Thus, a formulation comprising Compound I as taught by Edmonson et al. does not fall under the scope of the instant claims as newly amended. Further, in contrast to the instant claims which require the presence of  $\text{ZnCl}_2$ ; in addition to PACAP, Edmonson et al. teaches a salt only with respect to Compound I. That is to say, Edmonson et al. does not teach a separate salt in addition to the salt of the Compound I. In contrast, the instant claims recite a separate  $\text{ZnCl}_2$  salt, in addition to the option of having a zinc salt of PACAP. Further Edmonson et al. does not teach a dried formulation as required by independent claims 17, 26 and 34.

Pallenberg's teaching that peptide-copper complexes formulated for administration may contain DMSO, Maccacchini's teaching of a peptide formulation comprising an organic solvent and a transition metal, Bolin's teaching of organic solvents, TFA, HCl and lyophilization, and Igari's teaching of a water insoluble, polyvalent metal salt of a water soluble substrate, do not teach these missing limitations.

Because the cited references, when viewed individually or together, do not teach all the limitations of the claims as newly amended, Applicant submits that a prima facie obviousness has not been established as required by *In re Royka*. In light of the above remarks and claim amendments, Applicant respectfully requests reconsideration of the rejection of the instant claims.

In light of these remarks and claim amendments, Applicant respectfully requests reconsideration and withdrawal of the rejection.

### CONCLUSION

In view of the amendments and arguments presented above, Applicants believe the pending application is in condition for allowance. Should the Examiner believe that a telephone conversation with Applicants' attorney/agent would expedite prosecution of this application, she is cordially invited to call the undersigned attorney/agent. Please charge any required fee or credit any overpayment to Deposit Account No. 04-1105.

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Respectfully submitted,

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